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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/598,872

05/18/2007

Elan Ziv

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02/14/2011

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EXAMINER

BURK, CATHERINE E

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/598,872	ZIV, ELAN	
	<b>Examiner</b>	<b>Art Unit</b>	
	CATHERINE E. BURK	3735	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15, 16 and 18-37 is/are pending in the application.
- 4a) Of the above claim(s) 23-25, 30 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15, 16, 18-22, 26-29 and 32-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: ____.                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :2 November 2010, 6 January 2011, 20 January 2011, 27 January 2011, 2 February 2011.

### **DETAILED ACTION**

This Office action is responsive to the amendment filed on January 13<sup>th</sup>, 2011. The examiner acknowledges the amendments to claims 1, 26, and 35 and the cancellation of claim 14. Claims 1-13, 15, 16, and 18-37 are pending with claims 23-25, 30, and 31 having been withdrawn from consideration.

### **Claim Rejections - 35 USC § 102**

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-13, 15, 16, 20-22, 26-29, and 32-37 rejected under 35 U.S.C. 102(b) as being anticipated by Reimer (US 5618256 A).

3. Claim 1; Reimer discloses an apparatus sized and shaped for intra-vaginal insertion and arranged around a central axis for treating urinary incontinence. The apparatus -21- comprises a node -22- rotationally symmetrical about the central axis wherein the central axis runs perpendicular to the length of the device (i.e. from left to right in fig. 8 and passing through node -22-). The node is attached to a support section and an anchoring section, each labeled as arms -23-. The support section is the arm that contacts the anterior vaginal wall -30- while the anchoring section is the arm that contacts the posterior vaginal wall -32- (fig. 13 and col. 5, lines 60-65). In view of figs. 8, 13, and 18, the node is less than 30% of the entire length of the apparatus.

Art Unit: 3735

4. Claims 2 and 3; the node is approximately the area defined by bevel -24- (fig. 9), which is less than 15% of the length of the entire apparatus.
5. Claims 4 and 5; the apparatus may have three or more arms, for example four arms (col. 5, lines 11-13). In such an embodiment, two of the arms can be considered support arms and two can be considered anchoring arms.
6. Claims 6 and 7; the apparatus may comprise a coating that encapsulates the node, support section, and anchoring section (col. 3, lines 44-50); this coating constitutes a cover.
7. Claims 8 and 9; the entire apparatus, including the node, support, and anchoring sections, is flexible (col. 2, lines 53-58 and col. 5, lines 39-46).
8. Claims 10 and 11; the device also comprises a device displacer -28- attached to the support section (fig. 12).
9. Claim 12; the device may also comprise support struts -27- interlinking the support arms (col. 5, lines 26-30). The examiner notes that only one support strut is shown in fig. 10, however in embodiments using more than two arms (such as for example four arms) more than one support strut -27- would be present so as to act on each of the arms.
10. Claim 13; an applicator -33- or -37- adapted to insert the apparatus into a vagina is also included (figs. 14 and 18).
11. Claim 15; the length of each arm is preferably 40-50mm; therefore the length of the device in the compressed state, which is equal to the length of each individual arm (figs. 18), is also 40-50mm.

Art Unit: 3735

12. Claim 16; the support section may comprises a plurality of outwardly extending arms -23- (col. 5, lines 11-13) and an extending insert -27- adapted to increase the diameter of the support section by outwardly urging the arms (col. 5, lines 26-31).

13. Claims 20 and 21; the device also comprises a device displacer -28- attached to the support section (fig. 12).

14. Claim 22; an applicator -33- or -37- adapted to insert the apparatus into a vagina is also included (figs. 14 and 18).

15. Claim 32; when a plurality of arms are provided in the support section (similar to figs. 4-6) the arms are configured to lie on either side of the urethra.

16. Claim 33; a great number of support arms are possible, including at least 4. Reimer discloses the device may resemble an “octopus” which would imply up to eight arms are contemplated.

17. Claim 34; the support section does not completely occlude the vagina; therefore at least one channel is defined therein, allowing the flow of vaginal secretions past the apparatus (5, lines 64-65).

18. Claim 35; the size, or length, of the apparatus is configured to give at least mid-urethral support to a urethra (fig. 13).

19. Claim 36; if the device comprises at least 4 arms (2 for the anchoring section and 2 for the supporting section), then the device will resemble the shape of a plus sign. In the expanded state, the support section and anchoring section will each have a maximal diameter (i.e. a maximal distance between arms tips) greater than the maximal diameter of the node.

Art Unit: 3735

20. Claim 26; Reimer discloses a method of treating urinary incontinence comprising inserting an incontinence treating apparatus into a vagina and deploying the apparatus to render urethral (including mid-urethral) support (figs. 18 and 13). The apparatus comprises a node -22- that is rotationally symmetrical around a central axis of the apparatus as well as support and anchoring sections -23-, for supporting the urethra and resisting movement of the apparatus, attached to the node. In view of figs. 8, 13 and 18, the node is less than 30% of the length of the apparatus as a whole.
21. Claim 27; insertion is facilitated by an applicator -33- and -37 (figs. 14 and 18).
22. Claims 28 and 29; the method further comprises removing the apparatus using a device displacer -5- or -28- (col. 4, lines 37-39).
23. Claim 37; Reimer discloses that once the device is deployed, the device does not apply enough pressure to block the urethra absent an increase in intra-abdominal pressure (col. 2, line 65 - col. 3, line 1).

### **Claim Rejections - 35 USC § 103**

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

25. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reimer.
26. Claim 18; Reimer discloses that the device may include a cover in the form of a coating (col. 3, lines 44-50) and that the device (including the cover) is configured to provide urethral

Art Unit: 3735

support, therefore the cover is also configured to provide urethra support. Reimer also discloses that the urethra is not completely blocked when the device is inserted into the vagina and that the device is used to treat stress incontinence (col. 1, lines 14-15). Stress incontinence is the involuntary leakage of urine upon an increase in abdominal pressure. Although there will inherently be some minimal level of force applied to the urethra at all times due to the resilient nature of Reimer's device (which is also true of applicant's device), it would have been obvious to one of ordinary skill in the art at the time of the invention that Reimer's device is configured to apply a force to the urethra strong enough to block the flow of urine only during incidences of increased abdominal pressure because, under non-increased pressure situations, the user should be able to urinate normally and this would not be possible if the urethra is always blocked.

27. Claim 19; the cover taught by Reimer substantially encapsulates the entire device (col. 3, lines 44-50). This would include the support section and any extending inserts -27-.

### **Response to Arguments**

28. Applicant's arguments with respect to claims 1-13, 15, 16, 18-22, 26-29, and 32-37 have been considered but are moot in view of the new ground(s) of rejection.

### **Conclusion**

29. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after



Art Unit: 3735

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE E. BURK whose telephone number is (571) 270-7130. The examiner can normally be reached on Monday-Thursday 9:00 am - 7:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. E. B./  
Examiner, Art Unit 3735

/Charles A. Marmor, II/  
Supervisory Patent Examiner  
Art Unit 3735

Application/Control Number: 10/598,872  
Art Unit: 3735

Page 8